



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

6792 FEB 10 2004

Ms. Tracy Beckmann
Administrative Assistant
Earthlab, Inc.
dba Wise Woman Herbals
185 N. Mill
P.O. Box 279
Creswell, Oregon 97426

Dear Ms. Beckmann:

This is in response to your letters of January 9, 2004 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

Your letters state that the following statements will made for the following products:

Hawthorne Solid Extract	"Promotes balanced blood pressure..."
Gymnema capsules	"Supports normal blood sugar metabolism"
Hypo G Blood sugar support	"Supports normal blood sugar metabolism"
Hawthorne Tonic II	"Promotes...balanced blood pressure..."
Hawthorne Tonic I	"Promotes...balanced blood pressure..."
DM Compound	"Supports normal blood sugar metabolism"

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to claims about the control of blood glucose levels and blood pressure; that is, a claim that does not establish that the claims are about blood glucose levels or blood pressure that is already within normal limits implies that the product is intended to treat elevated blood glucose (diabetes) or blood pressure (hypertension), which are diseases. Therefore, because the claims you are making for these products represent that the products are intended to affect blood glucose and blood pressure but do not also include a statement about them being intended to affect blood glucose and blood pressure that are already in the normal ranges, they are implied disease claims.

915-0163

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21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

You also submitted a letter that states you intend to market a product named "Throat Mist" that is intended "...for promoting relief from dry throat." This product does not appear to meet the statutory definition of a dietary supplement contained in 21 U.S.C. 321(ff), and therefore, can not be marketed as a dietary supplement. We explain the basis for our opinion below.

The term "dietary supplement" is defined in 21 U.S.C. 321(ff). 21 U.S.C. 321(ff) provides that the term means a product (other than tobacco) intended to supplement the diet that bears or contains a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above ingredients. 21 U.S.C. 321(ff) further states that dietary supplements are intended for ingestion in a form described in 21 U.S.C. 350(c)(1)(B)(i) or in compliance with 21 U.S.C. 350(c)(1)(B)(ii), are not represented as conventional food or as a sole item of a meal or the diet, and are labeled as a dietary supplement.

An article that is taken orally but that exerts its intended effect in the mouth or throat prior to it being swallowed and absorbed is not "intended for ingestion." As stated above, the definition of dietary supplement in 21 U.S.C. 321(ff) states that a dietary supplement is a product "intended for ingestion." The term "ingestion" has been addressed by the court in United States v. Ten Cartons, Ener-B Nasal Gel, 888 F. Supp. 381, 393-94 (E.D.N.Y.), aff'd, 72 F.3d 285 (2d Cir. 1995), which states:

The ordinary and plain meaning of the term "ingestion" means to take into the stomach and gastrointestinal tract by means of enteral administration. See Stedman's Medical Dictionary (4th Lawyer's Ed. 1976) (defining ingestion as the "introduction of food and drink into the stomach."); Webster's Third New International Dictionary (1976) (defining ingestion as "the taking of material (as food) into the digestive system.")...

The interpretation of the term "ingestion" to mean enteral administration into the stomach and gastrointestinal tract is also supported by the language of the statutory sections immediately preceding and following section 350(c)(1)(B)(ii).

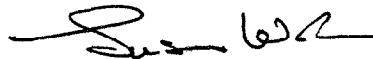
Page 3 - Ms. Tracy Beckmann

Section 350(c)(1)(B)(i) states that the vitamin must be intended for ingestion in tablet, capsule or liquid form. Each of these forms denotes a method of ingestion that involves swallowing into the stomach. Section 350(c)(2) states that a food is intended for ingestion in liquid form under section 350(c)(1)(B)(i) "only if it is formulated in a fluid carrier and is intended for ingestion in daily quantities measured in drops or similar small units of measure." This elaboration of "liquid form" also denotes ingestion by swallowing the fluid.

Therefore, because the term "ingestion" means introduced into the gastrointestinal tract, products that are intended to be taken in the mouth and affect a dry throat prior to being swallowed are not subject to regulation as dietary supplements because they are not "intended for ingestion." Moreover, because your product is not a dietary supplement and it appears to be an article (other than food) intended to affect the structure or any function of the body of man (i.e., provide relief from a dry throat), it appears that it is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(C), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research at the address given above.

Please contact us if we may be of further assistance.

Sincerely yours,



Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Seattle District Office, Office of Compliance, HFR-PA240

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA and 21 C.F.R./101.93**

EarthLab, Inc. dba

This notification is being filed on behalf of Wise Woman Herbs which is the producer [labeler, producer] of the product(s) which bear the statements identified in this notification. Its business address is: 185 N Mill, PO Box 279, Creswell, OR 97426. This notification is being made pursuant to Section 6 of DSHEA and 21 C.F.R./101.93. The dietary supplement product on whose label or labeling the statements appear is Throat Mist.

A. The text of each structure-function statement for which notification is now being given is:

(Statement 1): A staff favorite for promoting relief from dry throat.

(Statement 2):

(Statement 3):

B. The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
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- | | |
|----------------|---|
| 1.
2.
3. | <u>Echinacea angustifolia and purpurea (echinacea), propolis, E. angustifolia and purpurea glycer (echinacea)</u> |
|----------------|---|

C. The following identifies the brand name of each supplement for which a statement is made: (Complete this section only if the supplement(s) were not identified in Paragraph B.)

<u>Statement Number</u>	<u>Brand Name</u>
-----------------------------	-------------------

- | | |
|----------------|--|
| 1.
2.
3. | |
|----------------|--|

I, Tracy Beckmann, am authorized to certify this Notification on behalf of EarthLab, Inc. dba Wise Woman Herbs. I certify that the information presented and contained in this Notification is complete and accurate, and that EarthLab, Inc. dba Wise Woman Herbs has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: 1-9-04

By: Tracy Beckmann
[Name] Tracy Beckmann
[Title] Administrative Assistant

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA and 21 C.F.R./101.93

JAN 21 2004

This notification is being filed on behalf of EarthLab, Inc. dba
producer [labeler, producer] of the product(s) which bear the statements identified
in this notification. Its business address is: 185 N Mill, PO Box 279,
Creswell, OR 97402. This notification is being made
pursuant to Section 6 of DSHEA and 21 C.F.R./101.93. The dietary supplement
product on whose label or labeling the statements appear is DM Compound.

A. The text of each structure-function statement for which notification is now
being given is:

(Statement 1): Supports normal blood sugar metabolism.

(Statement 2):

(Statement 3):

B. The following summary identifies the dietary ingredient(s) or
supplement(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
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- | | |
|----|--|
| 1. | <u>Gymnema sylvestre (gymnema), Vaccinium spp. (blueberry/bilberry),</u> |
| 2. | <u>Oplopanax horridus (devil's club)</u> |
| 3. | |

C. The following identifies the brand name of each supplement for which a statement
is made: (Complete this section only if the supplement(s) were not identified in
Paragraph B.)

<u>Statement Number</u>	<u>Brand Name</u>
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- | | |
|----|--|
| 1. | |
| 2. | |
| 3. | |

I, Tracy Beckmann, am authorized to certify this Notification on behalf of EarthLab, Inc.
dba Wise Woman Herbals. I certify that the information presented and contained in this
Notification is complete and accurate, and that EarthLab, Inc. dba Wise Woman Herbals has
substantiation that each structure-function statement is truthful and not misleading.

Date Signed: 1-9-04

By: Tracy Beckmann
[Name] Tracy Beckmann
[Title] Administrative Assistant

27042

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA and 21 C.F.R./101.93

JAN 21 2004

EarthLab, Inc. dba

This notification is being filed on behalf of Wise Woman Herbals which is the
producer [labeler, producer] of the product(s) which bear the statements identified
in this notification. Its business address is: 185 N Mill, PO Box 279,
Creswell, OR 97426. This notification is being made
pursuant to Section 6 of DSHEA and 21 C.F.R./101.93. The dietary supplement
product on whose label or labeling the statements appear is Hawthorne Tonic I.

A. The text of each structure-function statement for which notification is now
being given is:

(Statement 1): Promotes healthy cardiac and kidney function, balanced blood
pressure, normal circulation and fluid elimination.

(Statement 2):

(Statement 3):

B. The following summary identifies the dietary ingredient(s) or
supplement(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
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- | | |
|----|--|
| 1. | <u>Crataegus spp. (hawthorn), Taraxacum officinale (dandelion leaf),</u> |
| 2. | <u>Selenicereus grandiflorus</u> |
| 3. | <u>(cactus/night-blooming cereus)</u> |

C. The following identifies the brand name of each supplement for which a statement
is made: (Complete this section only if the supplement(s) were not identified in
Paragraph B.)

<u>Statement Number</u>	<u>Brand Name</u>
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- | | |
|----|--|
| 1. | |
| 2. | |
| 3. | |

I, Tracy Beckmann, am authorized to certify this Notification on behalf of Earthlab, Inc.
dba Wise Woman Herbals I certify that the information presented and contained in this
Notification is complete and accurate, and that Earthlab, Inc. dba Wise Woman Herbals has
substantiation that each structure-function statement is truthful and not misleading.

Date Signed: 1-9-04

By: Tracy Beckmann
[Name] Tracy Beckmann
[Title] Administrative Assistant

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA and 21 C.F.R./101.93**

EarthLab, Inc. dba

JAN 21 2004

This notification is being filed on behalf of Wise Woman Herbals which is the producer [labeler, producer] of the product(s) which bear the statements identified in this notification. Its business address is: 185 N Mill, PO Box 279, Creswell, OR 97426. This notification is being made pursuant to Section 6 of DSHEA and 21 C.F.R./101.93. The dietary supplement product on whose label or labeling the statements appear is Hawthorne Tonic II

A. The text of each structure-function statement for which notification is now being given is:

- (Statement 1): Promotes healthy cardiac muscle, normal heart function
balanced blood pressure and normal circulation.
- (Statement 2):
- (Statement 3):

B. The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
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- | | |
|----------------|---|
| 1.
2.
3. | <u>Crataegus spp. (hawthorn), Tilia vulgaris (linden), Ginkgo biloba (gink)</u> |
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C. The following identifies the brand name of each supplement for which a statement is made: (Complete this section only if the supplement(s) were not identified in Paragraph B.)

<u>Statement Number</u>	<u>Brand Name</u>
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- | | |
|----------------|--|
| 1.
2.
3. | |
|----------------|--|

I, Tracy Beckmann, am authorized to certify this Notification on behalf of EarthLab, I
dba Wise Woman Herbals. I certify that the information presented and contained in this
Notification is complete and accurate, and that EarthLab, Inc. [company] dba Wise Woman Herbals has
substantiation that each structure-function statement is truthful and not misleading.

Date Signed: 1-9-04

By: Tracy Beckmann
[Name] Tracy Beckmann
[Title] Administrative Assistant

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA and 21 C.F.R./101.93**

EarthLab, Inc. dba

This notification is being filed on behalf of Wise Woman Herbs which is the 2004
producer [labeler, producer] of the product(s) which bear the statements identified
in this notification. Its business address is: 185 N Mill, PO Box 279,
Creswell, OR 97426. This notification is being made
pursuant to Section 6 of DSHEA and 21 C.F.R./101.93. The dietary supplement
product on whose label or labeling the statements appear is Hypo G Blood Sugar Support.

A. The text of each structure-function statement for which notification is now
being given is:

(Statement 1): Supports normal blood sugar metabolism.

(Statement 2):

(Statement 3):

B. The following summary identifies the dietary ingredient(s) or
supplement(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
-----------------------------	---

- | | |
|----------------|---|
| 1.
2.
3. | <u>Eleutherococcus senticosus (eleuthero/siberian ginseng), Glycyrrhiza glabra (licorice),</u>
<u>Avena sativa (oat)</u> |
|----------------|---|

C. The following identifies the brand name of each supplement for which a statement
is made: (Complete this section only if the supplement(s) were not identified in
Paragraph B.)

<u>Statement Number</u>	<u>Brand Name</u>
-----------------------------	-------------------

- | | |
|----------------|--|
| 1.
2.
3. | |
|----------------|--|

I, Tracy Beckmann, am authorized to certify this Notification on behalf of EarthLab, Inc.
dba Wise Woman Herbs. I certify that the information presented and contained in this
Notification is complete and accurate, and that EarthLab, Inc. dba Wise Woman Herbs has
substantiation that each structure-function statement is truthful and not misleading.

Date Signed: 1-9-04

By: Tracy Beckmann
[Name] Tracy Beckmann
[Title] Administrative Assistant

JAN 2 2004

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA and 21 C.F.R./101.93**

EarthLab, Inc. dba

This notification is being filed on behalf of Wise Woman Herbs which is the producer [labeler, producer] of the product(s) which bear the statements identified in this notification. Its business address is: 185 N Mill, PO Box 279, Creswell, OR 97426. This notification is being made pursuant to Section 6 of DSHEA and 21 C.F.R./101.93. The dietary supplement product on whose label or labeling the statements appear is Gymnema Capsules

A. The text of each structure-function statement for which notification is now being given is:

(Statement 1): Supports normal blood sugar metabolism.

(Statement 2):

(Statement 3):

B. The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
1.	<u>Gymnema sylvestre (gymnema)</u>
2.	
3.	

C. The following identifies the brand name of each supplement for which a statement is made: (Complete this section only if the supplement(s) were not identified in Paragraph B.)

<u>Statement Number</u>	<u>Brand Name</u>
1.	
2.	
3.	

I, Tracy Beckmann, am authorized to certify this Notification on behalf of EarthLab, Inc. dba Wise Woman Herbs. I certify that the information presented and contained in this Notification is complete and accurate, and that EarthLab, Inc. dba Wise Woman Herbs has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: 1-9-04

By: Tracy Beckmann
[Name] Tracy Beckmann
[Title] Administrative Assistant

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA and 21 C.F.R./101.93**

EarthLab, Inc. dba

This notification is being filed on behalf of Wise Woman Herbs which is the Producer [labeler, producer] of the product(s) which bear the statements identified in this notification. Its business address is: 185 N Mill, PO Box 279, Creswell, OR 97426. This notification is being made pursuant to Section 6 of DSHEA and 21 C.F.R./101.93. The dietary supplement product on whose label or labeling the statements appear is Hawthorne Solid Extract

A. The text of each structure-function statement for which notification is now being given is:

(Statement 1): Promotes balanced blood pressure and healthy cardiac function

(Statement 2):

(Statement 3):

B. The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
1.	<u>Crataegus spp. (hawthorn)</u>
2.	
3.	

C. The following identifies the brand name of each supplement for which a statement is made: (Complete this section only if the supplement(s) were not identified in Paragraph B.)

<u>Statement Number</u>	<u>Brand Name</u>
1.	
2.	
3.	

I, Tracy Beckmann, am authorized to certify this Notification on behalf of EarthLab, Inc. dba Wise Woman Herbs. I certify that the information presented and contained in this Notification is complete and accurate, and that EarthLab, Inc. dba Wise Woman Herbs has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: 1-9-04

By: Tracy Beckmann
[Name] Tracy Beckmann
[Title] Administrative Assistant